

K022393

JUN - 5 2003

stryker
ENDOSCOPY

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name: Laparoscope, General and Plastic Surgery
Common and Usual Name: Sidne™
Proprietary Name: Sidne™ System

This 510(k) summary and effectiveness is being submitted in accordance with requirements of SMMA 1990.

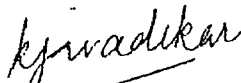
The Sidne™ System is substantially equivalent in safety and efficacy as the currently marketed HERMES OR Control Center. The HERMES OR Control Center was cleared under 510K# 991444.

The Stryker Sidne™ System is a medical device that is designed to allow the surgeon to control the state, selection, and settings of the surgical equipment it is networked with. Sidne™ is compatible with existing devices that are HERMES OR Control Center compatible.

The intent of the Sidne™ Control Center is to allow for voice control of medical device settings by the surgeon or operating room personnel, thereby eliminating the need for manual operation of those devices compatible with Sidne™, or relying upon verbal communications between the surgeon and other personnel in the operating room in order to adjust the surgical equipment. The Sidne™ System is intended for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery wherever a laparoscope /endoscope/arthroscope is indicated for use.

The Sidne™ System conforms to the following voluntary standards: EN 60601-1-1 Medical Electrical Equipment Part 1: General Requirements for Safety; EN 60601-1-1 Collateral Standard: Safety Requirements for Medical Electrical Systems; EN 60601-1-2 Collateral Standard: Electromagnetic Compatibility – Requirements and Tests; EN 60601-1-4 Collateral Standard: Programmable Electrical Medical Systems.

The technological differences between the Stryker Sidne™ System and the predicate HERMES device do not raise new issues of safety and efficacy of the predicate device. Therefore, the Stryker Sidne™ System is substantially equivalent to the currently marketed Computer Motion HERMES™ OR Control Center.


Kiran Javadekar
Senior Design Engineer
Stryker Endoscopy

Date: 6/03/2003



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN - 5 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kiran Javadekar
Senior Design Engineer
Stryker Endoscopy
5900 Optical Court
San Jose, California 95138

Re: K022393

Trade/Device Name: Merdoc™ System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ, HRX, KOG
Dated: March 31, 2003
Received: April 1, 2003

Dear Mr. Javadekar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

June 3, 2003

510(k) Number (if known): K022393

Device Name: Sidne™

Indications for Use:

The Stryker Sidne™ System is indicated for use with compatible endoscopic and general surgery devices. The Stryker Sidne™ System can be used in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery wherever a laparoscope /endoscope/arthroscope is indicated for use. A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic & thorascopic anterior spinal fusion, anterior cruciate ligament reconstruction, knee arthroscopy, shoulder arthroscopy, small joint arthroscopy, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization is indicated and examination of the evacuated cardiac chamber during performance of valve replacement. The users of Sidne™ are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, and urologists.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022393Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ☐